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10/808,078	03/24/2004	Mark Tsonton	END-5293	7086

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,078	TSONTON ET AL.	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on March 6, 2009. Examiner acknowledges the amendment of claims 1, 4, 9-11, 14, 16-18 and 20. Claims 1, 4 and 8-20 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

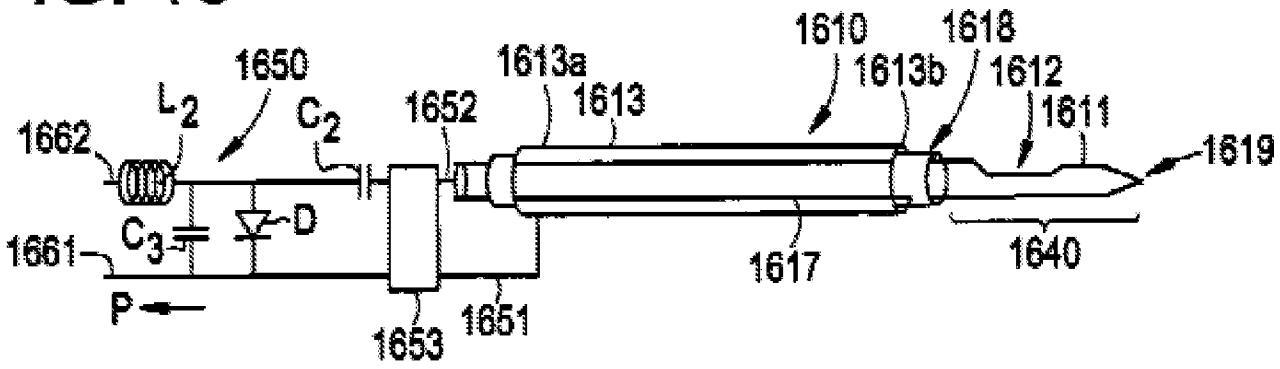
> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Kumar et al. (U.S. Patent Number 7,236,816).

In regard to claim 1, Kumar et al. disclose a biopsy device suitable for use with a magnetic resonance imaging machine (Abstract). The device includes a needle (1610) for receiving tissue therein. The needle comprises a distal and proximal needle segment. The distal needle segment disposed by Kumar et al. is designed to gain access inside the body of a patient to collect tissue samples from a specific target area. The distal needle segment of the Kumar et al. device further includes a side slot (1612) and a hollow core. The side slot is disposed laterally and is designed

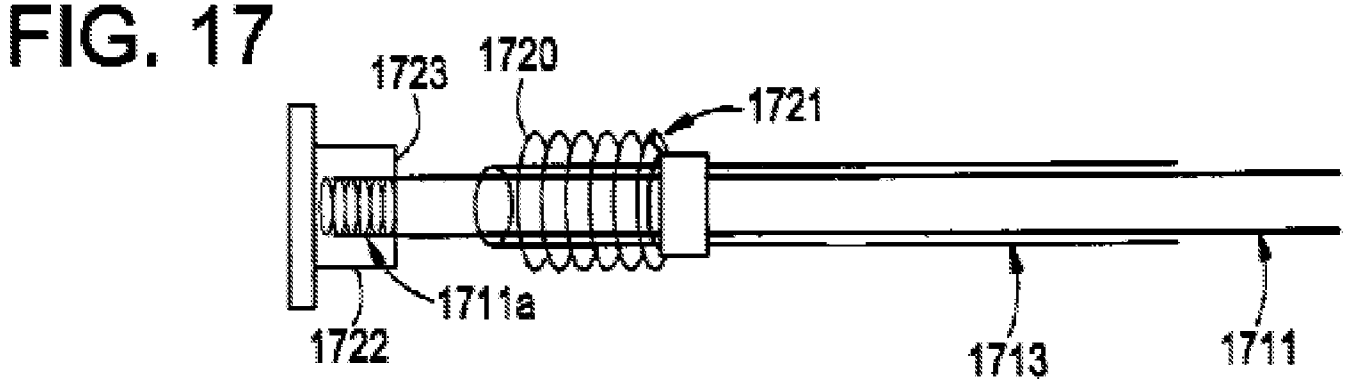
to receive tissue collected from the desired tissue site. The side slot (1612) is proximal to the piercing tip (1619) of the distal needle segment.

FIG. 16



Kumar et al. suggest the distal needle segment may include segments formed of a non-magnetic, non-metallic material (col. 23, lines 45-67; col. 24, lines 1-11). The proximal needle segment (1710) of the Kumar et al. device is coupled to the distal needle segment and is formed at least in part of a metal. The two coupled segments create a continuous lumen between the distal and proximal portions of the device (Figure 17).

FIG. 17



4. Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (U.S. Patent Number 6,758,824).

In regard to claim 19, Miller et al. disclose a biopsy device for use with a magnetic resonance imaging machine. The device comprises a distal needle segment (50) as shown in Figure 3A. This distal needle segment has a lateral tissue receiving port (55) and is distal from the target site when the device is in operation. Miller et al. suggest the distal needle segment may be formed of a non-metallic material. The device disclosed by Miller et al. further includes a proximal needle segment (15), which is formed at least in part of a metal. Miller et al. disclose the distal needle segment being coupled to the proximal needle segment. Furthermore, the two coupled segments create a continuous lumen between the distal and proximal cutter portions of the device (col. 7; col. 8, lines 1-21).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U.S. Patent Number 7,236,816) in view of Frederick et al. (U.S. Patent Number 6,017,356).

In regard to claims 8 and 10-14, Kumar et al. disclose a tissue removal device comprising a needle connected to a handpiece which is actuated to sever tissue at the target area. The biopsy device disclosed by Kumar et al. is suitable for use with magnetic resonance imaging machines (Abstract). Kumar et al. disclose the device comprising a needle having a distal needle segment and a proximal needle segment. Kumar et al. further suggest the proximal needle segment joined with the distal needle segment along a common longitudinal axis, forming a continuous cutter lumen. Although Kumar et al. suggest portions of the device be made of alternative materials, such as plastics or other non-metallic substances, to be compatible with magnetic resonance imaging systems, Kumar et al. do not disclose having a piercing tip made of ceramics or glass material. Kumar et al. also do not disclose the device creating a vacuum lumen which is connected to a vacuum port. Frederick et al. disclose a cutting device for penetrating into a body cavity of a patient. The device disclosed by Frederick et al. suggests the penetrating device being made of a ceramic material (col. 13, lines 28-57). Frederick et al. further disclose having a vacuum lumen which is connected to a vacuum port (col. 10, lines 54-65). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by Miller et al., to include a device having a penetrating tip portion made of ceramic material, similar to that disclosed by Frederick et al., to provide a device made of a biocompatible material which does not interfere with MRI procedures. Additionally, it would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar

to that disclosed by Miller et al., to include a device with a vacuum port, similar to that disclosed by Frederick et al., to assist with the collection of the biopsy sample.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U.S. Patent Number 7,236,816) in view of Frederick et al. (U.S. Patent Number 6,017,356) and in further view of Humphrey (U.S. Patent Number 5,607,401).

In regard to claim 4, the combined references of Kumar et al. and Frederick et al. disclose the features of the Applicant's invention as described above. Although the combined references disclose joining the distal needle segment with the proximal needle segment, the combination does not disclose having the distal needle segment molded over a portion of the proximal needle segment. Humphrey discloses a piercing device for penetrating into a body cavity of a patient. Humphrey further discloses attaching two segments of the needle together through a molding process. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by the combined references of Kumar et al. and Frederick et al., to include a needle made of two segments joined through a molding process, similar to that disclosed by Humphrey, to construct a continuous device while providing a secure and sealed joint between the two members.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U.S. Patent Number 7,236,816) in view of Frederick et al. (U.S. Patent Number 6,017,356) and in further view of Foerster et al. (U.S. Patent Application Publication Number 2002/0026201).

In regard to claim 9, the combined references of Kumar et al. and Frederick et al. disclose the features of the Applicant's invention as described above. Although the combined references

disclose having a vacuum lumen, the combination does not specifically disclose the vacuum port being located side by side with the cutter lumen. Foerster et al. disclose a biopsy device which includes a biopsy needle with a tissue receiving portion, an inner cutting cannula and a vacuum line which supplies vacuum to the ports of the tissue receiving portion of the biopsy needle. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by the combined references of Kumar et al. and Frederick et al., to include a vacuum port located side by side with the cutting lumen of a biopsy device, similar to that disclosed by Foerster et al., to provide another mechanism which assists with collection of the biopsy samples upon use of the device.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U.S. Patent Number 7,236,816) in view of Frederick et al. (U.S. Patent Number 6,017,356) and in further view of Gregoire et al. (U.S. Patent Number 5,944,673).

In regard to claim 15, the combined references of Kumar et al. and Frederick et al. disclose the features of the Applicant's invention as described above. The combination does not disclose having multiple passages extending from the vacuum to an outer surface of the needle. Gregoire et al. disclose a biopsy instrument with a vacuum source and an outer elongated hollow piercing needle. The needle of the Gregoire et al. device further includes a plurality of tissue receiving ports. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by the combined references of Kumar et al. and

Frederick et al., to include a multi-port needle, similar to that disclosed by Gregoire et al., to allow sampling of multiple tissue samples from a tissue site (Gregoire - col. 6, lines 17-39).

10. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (U.S. Patent Number 7,236,816) in view of Frederick et al. (U.S. Patent Number 6,017,356) and in further view of Miller et al. (U.S. Patent Number 6,638,235).

In regard to claims 16-18, the combined references of Kumar et al. and Frederick et al. disclose a biopsy device suitable for use with magnetic resonance imaging machines. The combined references fail to disclose the specific dimensions of the device. Miller et al. disclose an MRI compatible biopsy device. The device disclosed by Miller et al. comprises a needle having a distal needle segment and a proximal needle segment. Miller et al. suggest the proximal needle segment is formed of a metallic MRI compatible material such as titanium (col. 4, lines 59-63; col. 7, lines 31-42). The distal needle segment of the Miller et al. device includes a tissue receiving port (43) and is made of an alloy which may consist of a non-metallic material. Miller et al. further disclose the proximal needle segment joined with the distal needle segment along a common longitudinal axis, forming a continuous cutter lumen.

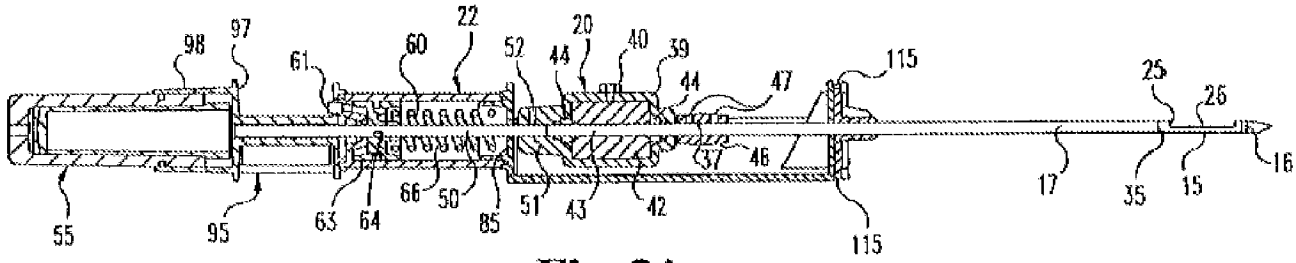


Fig. 3A

Miller et al. disclose the continuous lumen formed by the distal needle portion and the proximal needle portion creates a vacuum lumen and allows vacuum pressure to be maintained during use (col. 8 lines 26-60). The lumen comprises at least one passage extending to an outer surface of the needle. The device disclosed by Miller et al. includes a distal piercing tip (16) located distally from the tissue receiving port. Miller et al. disclose the features of the Applicant's invention as described above.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Humphrey (U.S. Patent Number 5,607,401).

In regard to claim 20, Miller et al. disclose the features of the Applicant's invention as described above. Although Miller et al. disclose joining the distal needle segment with the proximal needle segment; Miller et al. do not disclose having the distal needle segment molded over a portion of the proximal needle segment. Humphrey discloses a piercing device for penetrating into a body cavity of a patient. Humphrey further discloses attaching two segments of the needle together through a molding process. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a biopsy device for use with a magnetic resonance imaging machine, similar to that disclosed by Miller et al., to include a needle made of two segments joined through a molding process, similar to that disclosed by Humphrey, to construct a continuous device while providing a secure and sealed joint between the two members.

Response to Arguments

12. Applicant argues the Miller et al. reference does not disclose the claim limitations as amended including a lateral tissue receiving port positionable within the patient. Examiner submits the collection trap was interpreted to be the lateral tissue receiving port of the Miller et al. device. However, as amended would not meet the limitations of claim 16 since the lateral port (55) of Miller et al. device is not disposed proximally to the piercing tip and does not appear to be positionable within the patient. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant argues the Miller et al. device was misinterpreted as far as the directions and orientation of the device. Examiner respectfully disagrees that the Miller et al. reference was misinterpreted upon application of the Miller et al. device in the previous rejection. Examiner submits the interpretation of "proximal" and "distal" directions as described in the previous office action was applied according to the context of Applicant's claimed invention. Since these terms are relative to the application and orientation of the device, Examiner submits the reference was interpreted in context of a potential and applicable use of the device, which met the limitations as previously claimed.

14. Applicant argues the prior art references fail to disclose the claim limitations as amended including a cutter lumen and vacuum lumen extending side by side along at least a portion of the length of the cutter lumen. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant argues the Miller et al. device fails to disclose a vacuum lumen or a continuous lumen comprising at least one passage extending to an outer surface of the needle. Examiner

respectfully disagrees. The Miller et al. device discloses an aspiration port that is utilized to assist with collection of the biopsy samples. The device disclosed by Miller et al. can be a vacuum aspiration port as suggested by Miller et al. in the background section of the reference as well as throughout the reference. As described throughout the reference, Miller et al. uses a vacuum pressure interchangeably with an aspiration pressure (col. 7, lines 54-67; col. 8, lines 1-22). In the previous office action, Examiner directed attention to a passage in the Miller et al. reference which referred to the aspiration device as indication that the Miller et al. reference does use some sort of vacuum pressure to collect the tissue samples. Additionally, the Miller et al. reference describes reasoning behind creating the device including efforts to design a biopsy device that has a vacuum source that minimizes clogging issues and is capable of being used during MRI procedures without creating interference issues (col. 4, lines 9-21).

16. Applicant argues the Miller et al. reference teaches away from Applicant's invention because Miller et al. discloses that "with the exception of outer cannula (15), trocar tip (16) and inner cannula (17), every component of the biopsy device in accordance with the present invention can be formed of non-metallic material". Examiner respectfully disagrees. Examiner submits the Miller et al. suggests the trocar tip of the apparatus being formed of an alloy such as Inconel™, titanium or similar materials having similar magnetic properties. An alloy may consist of both metallic and non-metallic components. Upon substitution of material as suggested by Miller et al., one can incorporate an alloy which consists of metallic and non-metallic components. Examiner submits, since the material includes a non-metallic portion, the tip can be considered as "formed of a non-metallic, first material" as required by the limitations of the claimed invention.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736